K130193

JUN 1 4 2013

SECTION 5: 510(k) SUMMARY STATEMENT

This 510(k) summary is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990, 21 CFR 807.92

1. **General Information**

Date of Submission: January 25, 2013

Submitted By: Solta Medical, Inc.
25881 Industrial Blvd.
Hayward, CA 94545

Contact Person: Raymond Lee
Sr. Director, Regulatory Affairs
510-259-7159 (Direct Phone)
510-780-4931 Fax
rflee@solta.com

2. **Trade/Proprietary Name of Device:**

Trade Name:	Fraxel® DUAL 1550/1927 Laser System
Common Name:	Laser Surgical Instrument
Regulation Number	878.4810
Product Code:	GEX
Device Panel:	General Surgery/Restorative Devices
Device Classification:	Class II

3. **Legally Marketed Predicate Devices for Claimed Equivalence:**

Name: Fraxel® DUAL 1550/1927 Laser System
510(k) #: K101490

Name: Fraxel® Re:fine Laser System
510(k) #: K063808

4. **Device Description**

The Fraxel DUAL 1550/1927 nm Laser System consists of a 1550 nm laser source and a 1927 nm laser source with fiber delivery and control by an embedded processor for use in dermatological procedures. The laser system uses scanning and focusing optics to deliver a controlled pattern of thermal energy to the epidermis and dermis. Device accessories include tip kits and pre-treatment solution.

5. Indications for Use Statement

1550 nm: The Fraxel 1550 nm laser is indicated for use in dermatological procedures requiring the coagulation of soft tissue, as well as for skin resurfacing procedures. It is also indicated for treatment of dyschromia and cutaneous lesions, such as, but not limited to lentigos (age spots), solar lentigos (sun spots), actinic keratosis, and melasma, and for treatment of periorbital wrinkles, acne scars and surgical scars.

1927 nm: The Fraxel 1927 nm laser is indicated for use in dermatological procedures requiring the coagulation of soft tissue, treatment of actinic keratosis, and treatment of pigmented lesions such as, but not limited to lentigos (age spots), solar lentigos (sun spots) and ephiledes (freckles).

6. Substantial Equivalence Comparison

Indications for Use

Substantial equivalence for the Fraxel DUAL 1550/1927 nm Laser System and Accessories is supported by the predicate devices listed in this submission, which have identical or similar indications statements. Clinical performance data confirmed that the Fraxel DUAL 1550/1927 nm Laser System performs as intended and that no new issues of safety and effectiveness are introduced.

Technological Characteristics

Key technological characteristics of the Fraxel DUAL 1550/1927 nm Laser System, such as energy type and operating principle, are identical to the Fraxel DUAL 1550/1927 nm Laser System described in submission K101490. No changes were made to the mode of operation and fractional delivery of the 1550 and 1927 nm laser sources.

Performance Data

A clinical study was conducted to support a determination of substantial equivalence to the predicate device, the Fraxel DUAL 1550/1927 Laser System (K101490). The clinical performance data confirmed that the Fraxel DUAL 1550/1927 Laser System performs as intended and that the expansion of the new 1927 nm indications do not raise new issues of safety and effectiveness.

Substantial Equivalence Statement

When compared to the predicate devices, the additional indications for use of the Fraxel Dual 1550/1927 Laser System do not raise new issues of safety and effectiveness.

Therefore, based on the similarities in technological features, mode of operation, laser-tissue interaction, clinical performance, and intended use, the modified Fraxel DUAL 1550/1927 Laser System is substantially equivalent to the predicate devices marketed under the Federal Food, Drug and Cosmetic Act.

7. Conclusion

The Fraxel DUAL 1550/1927 nm Laser System is substantially equivalent to the predicate devices currently marketed in accordance with the Federal Food, Drug and Cosmetic Act. Based on clinical performance data, the addition to the indications for use raises no new safety and effectiveness questions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

June 14, 2013

Solta Medical, Inc.
% Mr. Raymond Lee
Senior Director, Regulatory Affairs
25881 Industrial Boulevard
Hayward, California 94545

Re: K130193
Trade/Device Name: Fraxel Dual 1550/1927 nm Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: April 17, 2013
Received: April 18, 2013

Dear Mr. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

FOR Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130193

Device Name: Fraxel DUAL 1550/1927 nm Laser System and Accessories

Indications For Use:

1550 nm: The Fraxel 1550 nm laser is indicated for use in dermatological procedures requiring the coagulation of soft tissue, as well as for skin resurfacing procedures. It is also indicated for treatment of dyschromia and cutaneous lesions, such as, but not limited to lentigos (age spots), solar lentigos (sun spots), actinic keratosis, and melasma, and for treatment of periorbital wrinkles, acne scars and surgical scars.

1927 nm: The Fraxel 1927 nm laser is indicated for use in dermatological procedures requiring the coagulation of soft tissue, treatment of actinic keratosis, and treatment of pigmented lesions such as, but not limited to lentigos (age spots), solar lentigos (sun spots) and ephiledes (freckles).

Prescription Use X AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden
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(Division Sign-Off) for MXM

Division of Surgical Devices

510(k) Number K130193